

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NUVASIVE, INC.,

Plaintiff,

v.

GLOBUS MEDICAL, INC.,

Defendant.

C. A. No. 10-849-LPS

JURY TRIAL DEMANDED

FIRST AMENDED COMPLAINT FOR PATENT INFRINGEMENT

Pursuant to Federal Rule of Civil Procedure 15(a), Plaintiff NuVasive, Inc. (“NuVasive”), by its attorneys, files this First Amended Complaint (“Complaint”) for patent infringement against defendant Globus Medical, Inc. (“Globus”) and alleges as follows:

NATURE OF THE ACTION

1. This is a civil action arising out of Globus’ patent infringement in violation of the Patent Laws of the United States, 35 U.S.C. §§ 271 and 281-285.

THE PARTIES

2. NuVasive is a Delaware corporation having its principal place of business at 7475 Lusk Blvd., San Diego, California 92121.

3. On information and belief, Globus is a Delaware corporation having its principal place of business at 2560 General Armistead Avenue, Audubon, Pennsylvania 19403.

JURISDICTION AND VENUE

4. This Court has subject matter jurisdiction over NuVasive’s patent infringement claims under 28 U.S.C. § 1331 and 1338(a).

5. This Court has personal jurisdiction over Globus because Globus is a Delaware corporation.

6. Upon information and belief, Globus is doing business in this judicial district providing an additional basis for the Court's exercise of personal jurisdiction over Globus.

7. Venue is proper in this district under 28 U.S.C. §§ 1391(b), (c), and 1400(b).

FACTUAL ALLEGATIONS

8. NuVasive is the originator and developer of the XLIF[®] Surgical Technique ("XLIF") for minimally disruptive spine surgery. XLIF is an acronym for eXtreme Lateral Interbody Fusion. NuVasive's XLIF technique allows for a direct lateral retroperitoneal approach to the intervertebral disc space. Direct lateral retroperitoneal approach means that the surgical approach to the spine is: (a) lateral, meaning from the patient's side rather than the traditional approaches through the patient's back (so-called "posterior" approach) or abdomen (so-called "anterior approach"); and (b) retroperitoneal, meaning behind or posterior to the peritoneum, which encloses the bowels.

9. XLIF incorporates the use of two systems that enable safe and reproducible minimally disruptive spine surgery: (1) the MaXcess[®] III Access System ("MaXcess"), and (2) the NeuroVision[®] System and associated electrified dilators ("NeuroVision").

10. MaXcess is a 3-bladed surgical retractor that allows the fundamentals of conventional surgical techniques to be achieved through a small opening in the patient's body. MaXcess, however, eliminates the requirements of operating coaxially through tubular portals commonly encountered in minimally invasive surgery performed through tubes (commonly referred to as cannulas or cannulae). The 3 blades of MaXcess include a posterior blade (located "rearwards" or towards the back of the patient), a caudal blade (located "downwards" or towards

the feet of the patient), and a cephalad blade (located “upwards” or towards the head of the patient).

11. NeuroVision is a surgeon-driven technology that provides dynamic, discrete information on nerve location and condition. NeuroVision is used during the XLIF procedure to enable a safe trajectory past the nerves near the spine by communicating nerve proximity and directional information to the surgeon performing the XLIF procedure. NeuroVision is used in conjunction with NuVasive’s sequential dilators. Those dilators include directional electrodes at their distal ends. The distal end electrodes permit the surgeon not only to determine the proximity of the dilator to the nerves, but also to actively redirect the dilator to avoid the nerves en route to the disc space. Similarly, the MaXcess retractor’s posterior blade includes a distal end electrode for continuous monitoring of the proximity of that blade to nerves. This enables the surgeon to locate and avoid the bundle of nerves known as the lumbar plexus while accessing the disc space, as well as monitor nerves adjacent to the posterior blade during the surgery to assess, for example, the impact of prolonged retraction.

12. Together, these systems enable maximum surgical access to the intervertebral disc space while minimizing the soft tissue disruption typically associated with open surgery. Because MaXcess allows the surgeon relatively large, but safe, access to the disc space, implants larger than those implanted via a minimally invasive procedure can be used. These larger implants provide the surgeon with the ability to indirectly decompress nerves and restore disc height and alignment. The XLIF procedure results in substantially less trauma and significantly improved results to the patient undergoing spinal disc replacement and/or other spinal surgeries when compared with traditional open, minimally invasive, anterior or posterior procedures.

13. NuVasive began developing XLIF in 2002 and first introduced it in 2004. XLIF has since proliferated into a globally accepted surgical technique with over 50,000 cases to date. XLIF has enjoyed this success because it provides numerous benefits to the patient, the surgeon, and the hospital over the previously used approaches to spinal surgery including: reduced blood loss, reduced trauma, briefer anesthesia, briefer hospitalization, briefer recovery, and improved outcomes. NuVasive's efforts in developing XLIF and teaching surgeons of the benefits of XLIF has resulted in the issuance of several United States patents, including United States Patent Nos. 7,691,057 B2 ("the '057 patent") and 7,819,801 ("the '801 patent").

14. The broad adoption of the XLIF procedure has resulted in substantial growth for NuVasive. In the span of a decade, NuVasive has gone from a small company operating in the garage of its founder to a global company with a market capitalization of over \$1 billion and 2009 sales in excess of \$370 million. NuVasive's remarkable success has not gone unnoticed by NuVasive's competitors and would-be competitors.

15. Globus markets a surgical procedure it refers to as "LLIF." LLIF is an acronym for Lateral Lumbar Interbody Fusion. Like XLIF, LLIF is a direct lateral retroperitoneal intervertebral disc procedure. On information and belief, Globus promotes the LLIF procedure as equivalent to XLIF. On information and belief, by offering cut-rate "introductory offers" to hospitals and surgeons, Globus seeks to benefit from NuVasive's multi-million dollar, decade-long investment in research, development, scientific study, and marketing efforts. These efforts by NuVasive succeeded in convincing surgeons of the superiority of the direct lateral approach to the spine over traditional methods of spinal surgery.

16. Globus promotes, sells and offers for sale instruments and implants, including instruments and implants under the trademarks TransContinental[®] and MARS[®] 3V, for the performance of LLIF.

17. Globus describes TransContinental[®] as a comprehensive system of instruments and implants designed to treat degenerative lumbar conditions via a minimally invasive anterior retroperitoneal approach. As illustrated in detail below, the LLIF procedure that incorporates the use of the TransContinental[®] is a direct lateral approach. This is reflected in the name LLIF – *Lateral* Lumbar Interbody Fusion.

18. Globus describes TransContinental[®] for use in a surgical technique that allows for placement of a large interbody cage across the disc space while eliminating the manipulation of vascular, neural and bony structures required in more traditional anterior and posterior procedures.

19. Globus describes TransContinental[®] as including:

a. Four insulated cannulas. The respective diameter of these instruments is 7mm, 13mm, 18mm, and 23mm. The cannulas have depth markings for blade length estimation. The cannulas include stimulation clip connections for connection to electrodes.

b. Posterior blades. The set of posterior blades range in length from 40 mm to 170 mm. The posterior blades include a pair of slots for use with disc shims, which are also part of TransContinental[®].

c. Caudal and Cephalad ("CC") blades. The "CC" blades range in length from 40 mm to 170 mm. The "CC" blades include a pair of slots for use with lengthening shims, which are also part of TransContinental[®].

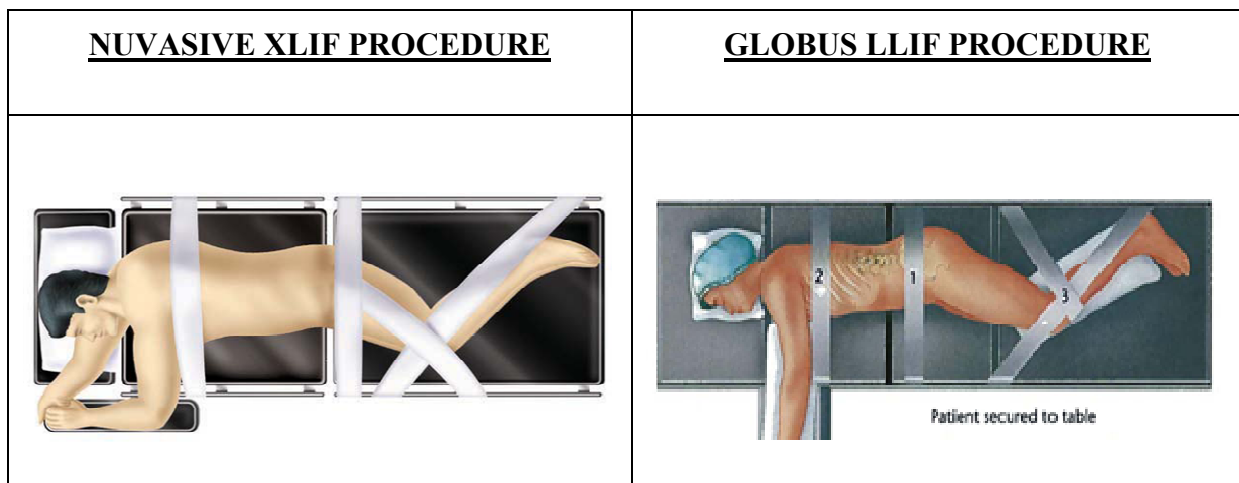
20. Globus describes the MARS[®] 3V retractor as a versatile and variable vision system that gives unprecedented control of tissue retraction during the entire procedure.

21. Globus describes the MARS[®] 3V retractor as providing gentle retraction of soft tissue while the TransContinental[®] implant design ensures ease of insertion and optimal endplate contact.

22. The illustrations below show a comparison between NuVasive's innovative XLIF procedure (on the left) and Globus' infringing LLIF procedure (on the right).


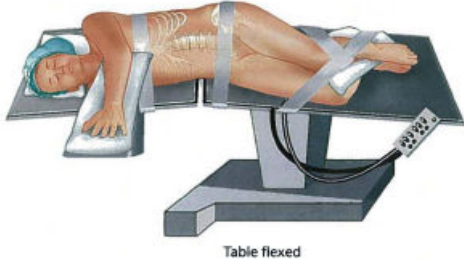
23. During NuVasive's XLIF procedure, the "patient is placed on a bendable surgical table in a direct lateral decubitus (90°) position so that the iliac crest is directly over the table break."

24. The Globus TransContinental Surgical Technique instructs surgeons that "[t]he patient is placed on a flexible surgical table in a true 90° right lateral decubitus position so that the iliac crest is just over the table break, as shown."



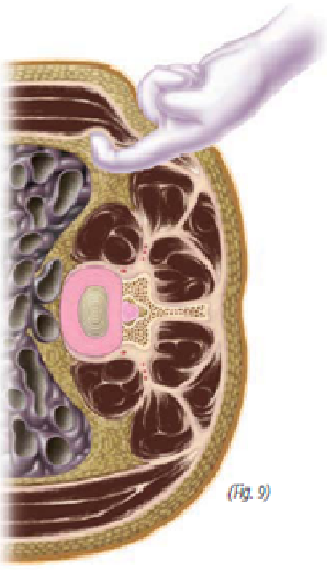
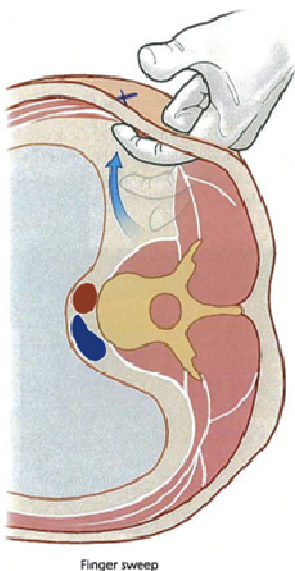
25. In NuVasive's XLIF procedure, the surgeon then flexes the surgical table to increase the "distance between the iliac crest and the ribs in order to gain access to the disc."

26. The Globus TransContinental Surgical Technique instructs surgeons to flex the surgical table "to open the interval between the 12th rib and the iliac crest and provide direct access to the disc space as shown below."

<u>NUVASIVE XLIF PROCEDURE</u>	<u>GLOBUS LLIF PROCEDURE</u>
	

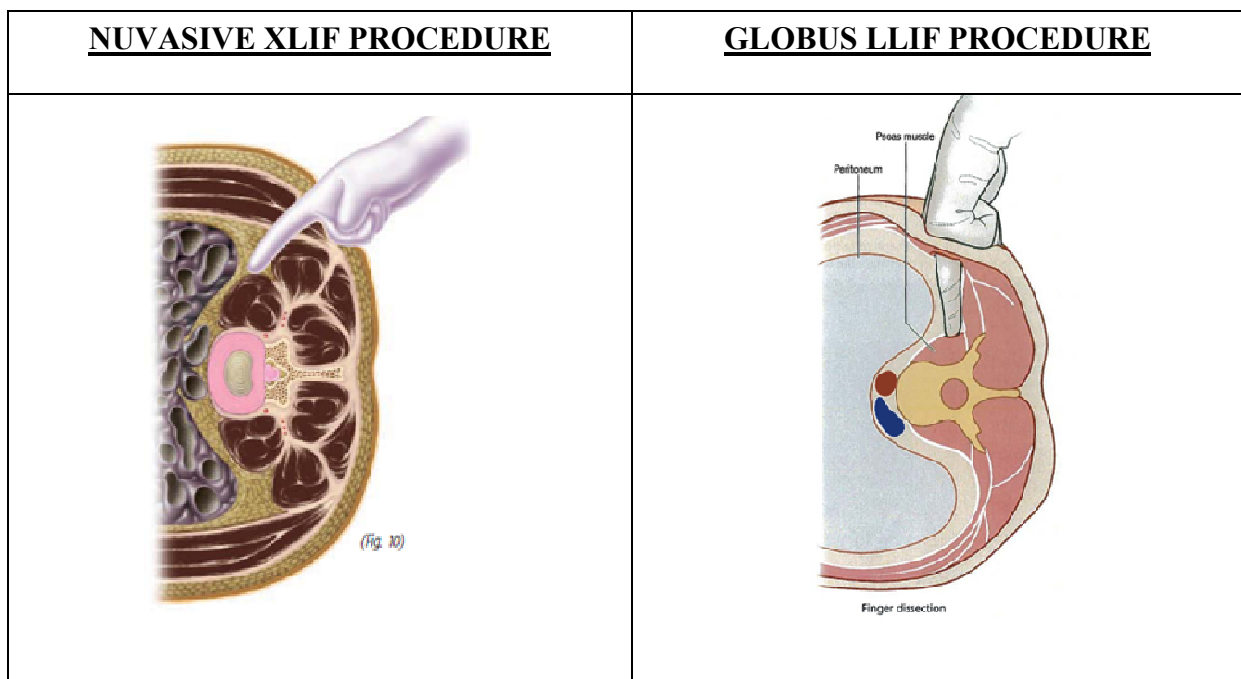
27. During NuVasive's XLIF procedure, "[o]nce inside the retroperitoneal space, the [surgeon's] index finger is used to create space and sweep the peritoneum anteriorly."

28. The Globus TransContinental Surgical Technique instructs surgeons that "[a]fter accessing the retroperitoneal space, the index finger is used to sweep the peritoneum anteriorly and ensure that the abdominal contents have fallen forward."

<u>NUVASIVE XLIF PROCEDURE</u>	<u>GLOBUS LLIF PROCEDURE</u>
	

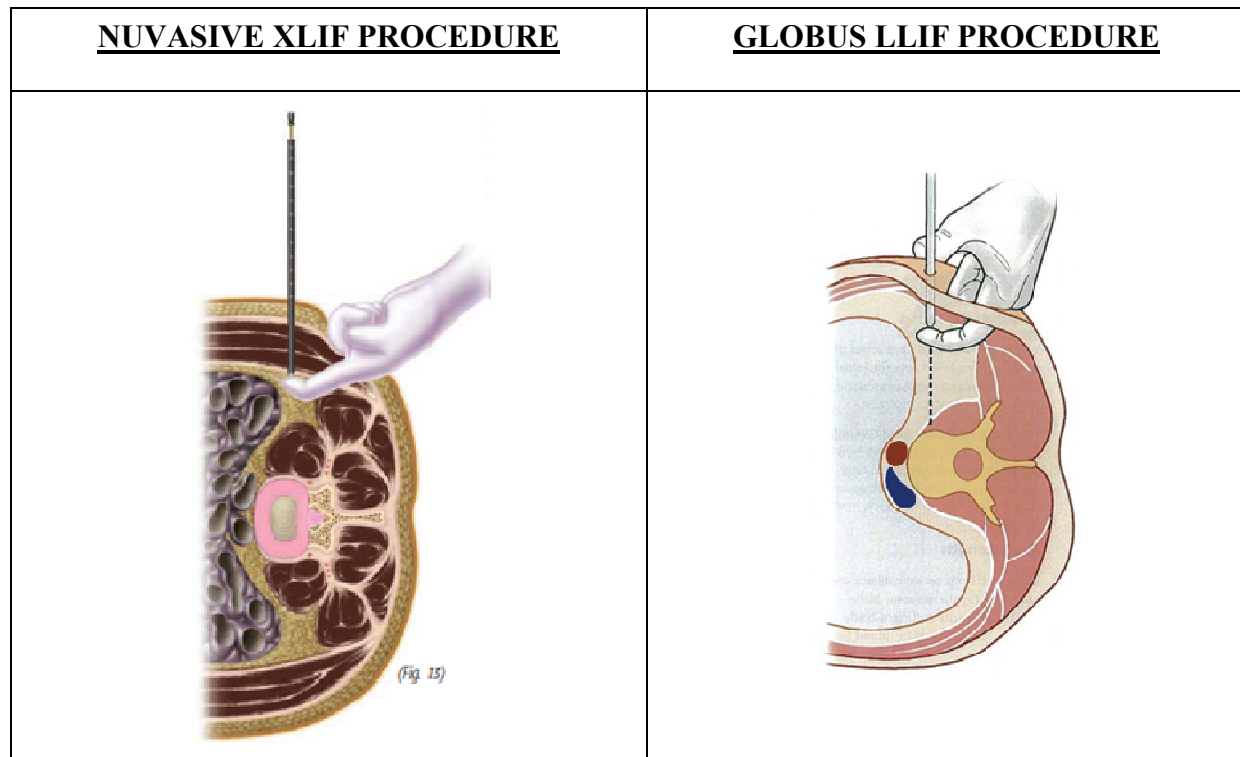
29. During NuVasive's XLIF procedure, when "the peritoneum is released, the [surgeon's] finger is then used to palpate the psoas muscle, or anterior tip of the transverse process." "Once the psoas muscle location is identified, the index finger is swept up to the inside abdominal wall underneath the direct lateral skin mark. This step ensures that a safe pathway exists between the abdominal wall and the psoas muscle."

30. The Globus TransContinental Surgical Technique instructs surgeons that "[d]igital palpation of the psoas muscle is performed and the lateral vertebral body contour localized."



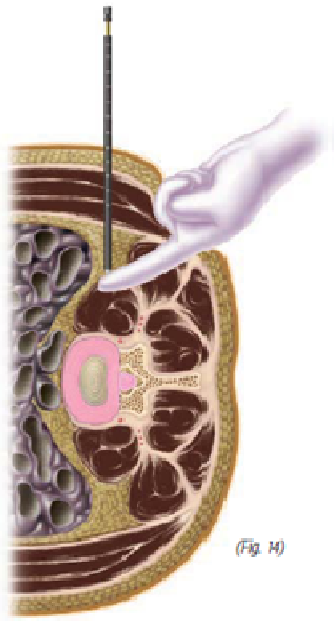
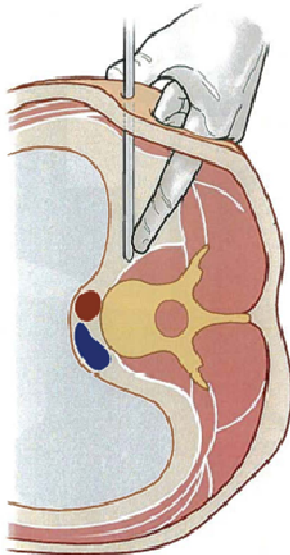
31. During NuVasive's XLIF procedure, a second, direct lateral incision is made where the surgeon's index finger sweeps up and pushes against the abdominal wall. At this second incision, the initial NeuroVision Dilator is introduced.

32. The Globus TransContinental Surgical Technique instructs surgeons that “[a] second incision is made at the access mark and the initial dilator is introduced to meet the index finger already inside the retroperitoneal space.”



33. During NuVasive’s XLIF procedure, “the [surgeon’s] index finger that is inside the retroperitoneal space is then used to escort the initial Dilator safely down to the psoas muscle.”

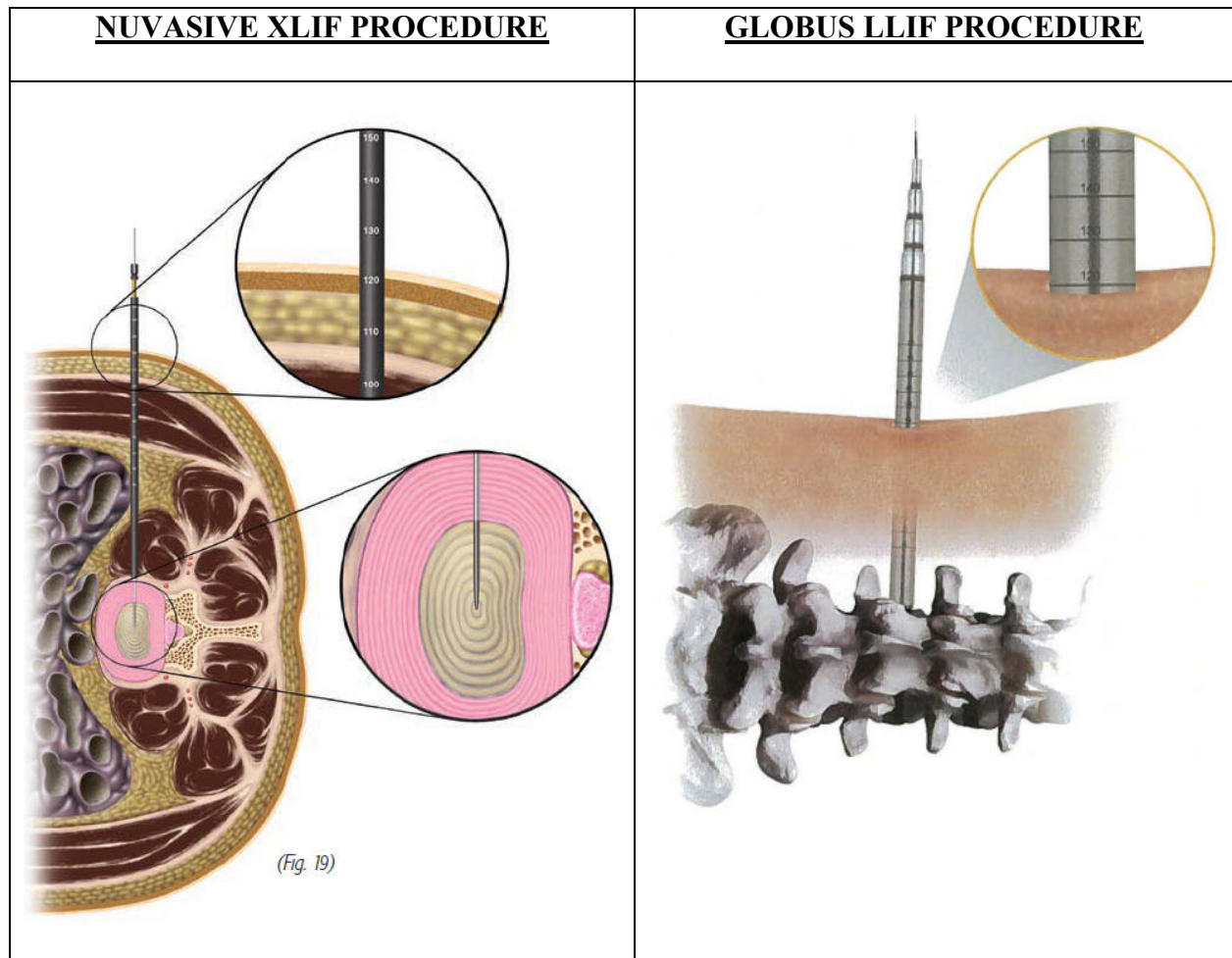
34. The Globus TransContinental Surgical Technique instructs surgeons that “[u]sing the index finger, the initial dilator is safely guided down to the surface of the psoas muscle as shown below.”

<u>NUVASIVE XLIF PROCEDURE</u>	<u>GLOBUS LLIF PROCEDURE</u>
 <p>(Fig. 14)</p>	

35. It is at this stage in the procedure that the surgeon begins moving the first of a series of cannulas through the psoas muscle located near the spine. During NuVasive's XLIF procedure, "[f]ollowing confirmation of position, a K-Wire is introduced about halfway into the disc space to secure position (Fig. 19). Depth markings on the Dilator indicate the size of the appropriate-length Blades to be attached to the MaXcess[®] Access Driver. The next two NeuroVision[®] Dilators (magenta, blue) are subsequently introduced over the initial Dilator using a twisting motion. NeuroVision is used as with the previous Dilator to determine nerve proximity."

36. The Globus TransContinental Surgical Technique instructs surgeons that "[o]nce the initial dilator has reached the surface of the psoas muscle, proper positioning is confirmed using lateral fluoroscopy. The center of the disc space should be targeted in order to avoid the

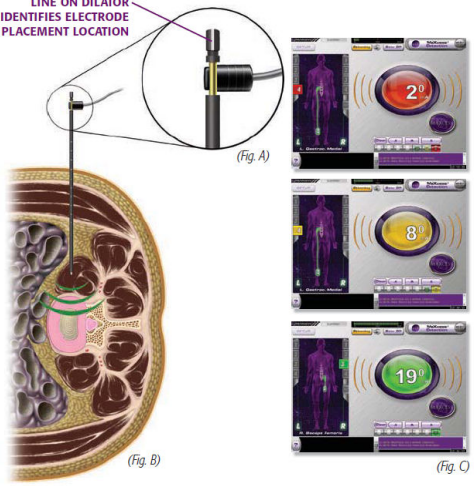

anterior vascular structures and posterior neural elements as shown at right. The initial dilator can then be inserted through the psoas muscle and docked centrally over the disc space. AP fluoroscopy is used to confirm proper initial dilator alignment and a k-wire is inserted through the initial dilator into the disc space in preparation for sequential dilation. . . . With the k-wire in place, a series of cannulas are passed over the initial dilator spreading the psoas muscle to prepare for retractor insertion.”



37. In NuVasive’s XLIF procedure, the surgeon uses NeuroVision to help determine the location, direction, and proximity of spinal nerves running through the psoas muscle as the dilator moves through the psoas muscle toward the spine. In NuVasive’s XLIF procedure, three successive dilators, each larger in diameter than the previous, are introduced through the lateral

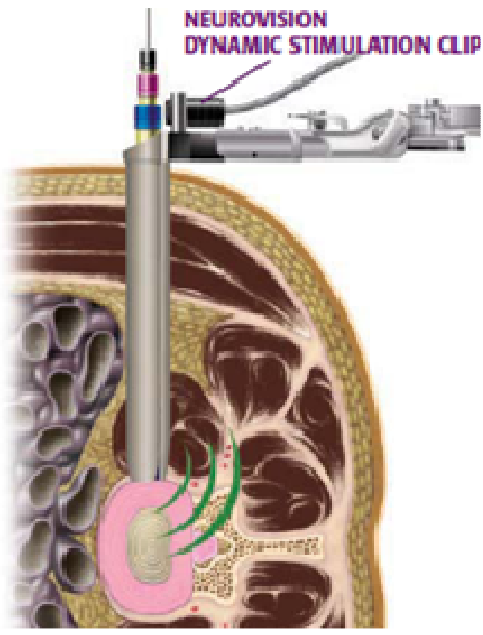
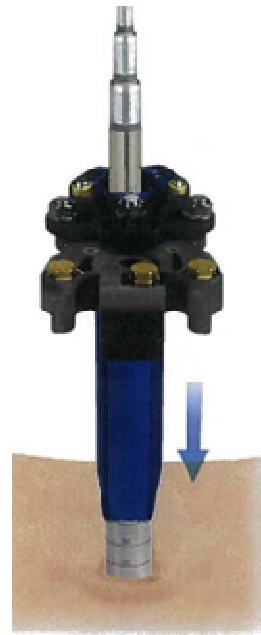
incision, through the psoas muscle and to the spine. For each dilator used during the XLIF procedure, NeuroVision is used to aid the surgeon with the location, direction and proximity of nerves in the psoas muscle.

38. On information and belief, Globus instructs physicians to monitor the patient's nerves during the insertion of the insulated cannulas during the LLIF procedure. On information and belief, Globus produced and provides to surgeons a document entitled "Neuromonitoring Protocol-Lateral Lumbar Interbody Fusion Procedure." This document describes the use of "real-time stimulation (Triggered EMG) as a cannula is percutaneously advanced through the psoas until it reaches the disc interspace. This is performed to ensure that the cannulas do not come in contact with monitored neural tissue as they are advanced." Globus instructs surgeons that the "stimulation clip should be attached to the exposed metal portion at the top of the initial cannula and stimulated during advancement through the psoas muscle. This step should be repeated for each of the gradually dilating cannulas. ... Constant monitoring of the signal response should be observed during advancement of the cannulas and the neuromonitoring technician should be in constant communication with the surgical team if a CMAP is elicited and a re-direction of the cannulas is required."

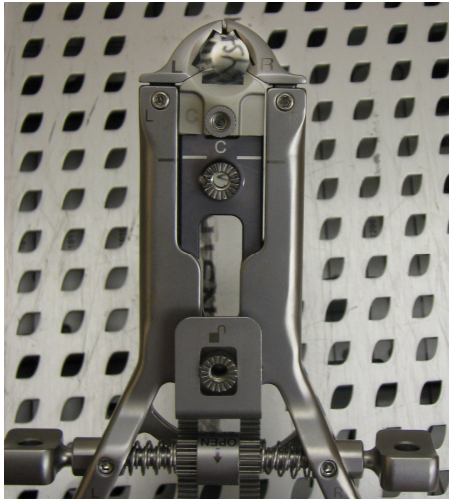
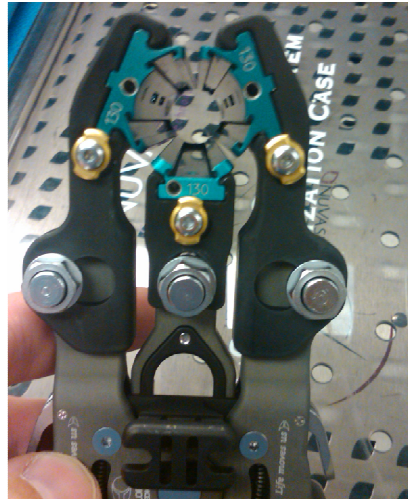
<u>NUVASIVE XLIF PROCEDURE</u>	<u>GLOBUS LLIF PROCEDURE</u>
 <p>LINE ON DILATOR IDENTIFIES ELECTRODE PLACEMENT LOCATION</p> <p>(Fig. A)</p> <p>(Fig. B)</p> <p>(Fig. C)</p>	

39. After the dilators have sequentially been introduced through the lateral incision, through the psoas muscle and are at the intervertebral disc space, the surgeon then introduces a specially designed retractor to provide access to the intervertebral disc space. In NuVasive's XLIF procedure this is the MaXcess. The MaXcess works in combination with NuVasive's NeuroVision to again ensure that the MaXcess does not come into contact with any nerves as it moves through the psoas muscle toward the spine.

40. The Globus TransContinental Surgical Technique instructs surgeons to "[e]nsure that the retractor is in the fully closed position and the blades are securely attached to the frame. The skin and fascia incision should allow the blades to retract and angulate. Slide the retractor over Insulated Cannula C and apply gentle downward pressure on the frame."

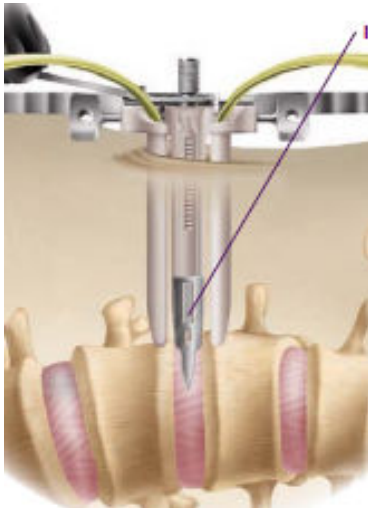
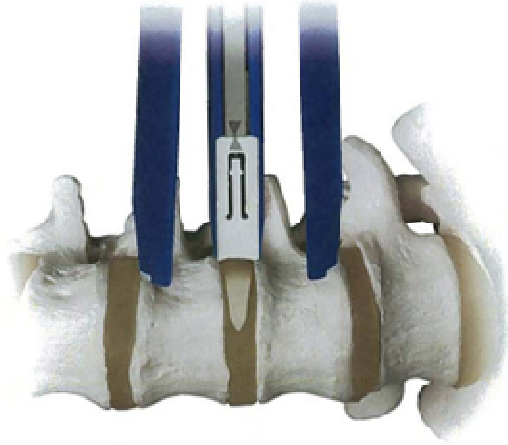
<u>NUVASIVE XLIF PROCEDURE</u>	<u>GLOBUS LLIF PROCEDURE</u>
	

41. The photographs below compare the NuVasive MaXcess and Globus MARS[®] 3V.

<u>NUVASIVE MAXCESS III</u>	<u>GLOBUS MARS[®] 3V</u>
	

42. During NuVasive's XLIF procedure, once at the spine, the blades of the retractor are "expanded approximately three 'clicks'" to widen the access space available for the surgeon. Subsequently, an "Intradiscal Shim may be placed into the disc space to further stabilize the [MaXcess III] retractor."

43. The Globus TransContinental Surgical Technique instructs surgeons that "[f]or additional retractor stability, the Intradiscal Shim can be inserted into the disc space through the posterior blade to increase retractor stability when expanding blades for increased exposure as shown at right." The Globus TransContinental Surgical Technique also instructs surgeons that the retractor blades can be expanded "using the 10mm Socket Driver to turn the respective gold hex nut in the direction indicated by the arrow."

<u>NUVASIVE XLIF PROCEDURE</u>	<u>GLOBUS LLIF PROCEDURE</u>
	

44. During NuVasive's XLIF Procedure, once the MaXcess III retractor is locked into place and the blades expanded, various tools are used to "thoroughly evacuate the disc and prepare the endplates for fusion." During the XLIF procedure, the "XLIF Distractor and Paddle

Sizers are used to distract the disc space and gauge the appropriately sized Trial.” The Trial is then inserted and centered into the evacuated disc space. “Proper anterior/posterior position is verified using lateral fluoroscopy.” Once the surgeon is satisfied with the placement and fit of the Trial, the Surgeon removes the Trial from the disc space. The surgeon then selects the corresponding implant, fills the implant with “graft material,” and places the implant into the “disc space while monitoring under AP fluoroscopy and NeuroVision® Run EMG.”

45. The Globus TransContinental Surgical Technique instructs surgeons to “remove the intervertebral disc and osteophytes as needed. The Disc Box Cutter, Rotary Cutter, Disc Rongeurs, Kerrisons, Curettes, Scrapers and Rasps are provided for disc removal and endplate preparation as shown at right.” The Globus TransContinental Surgical Technique further instructs surgeons that “[t]o determine the appropriate graft size for the desired segment, first insert the smallest Trial into the disc space, moving to larger trials as needed. Determine which trial best fits the prepared disc space.” The Globus TransContinental Surgical Technique further instructs surgeons to “[u]se AP fluoroscopy to confirm the implant is centered and lateral fluoroscopy to ensure that the implant is in the appropriate AP position.” The Globus TransContinental Surgical Technique next instructs surgeons to “[s]elect the appropriate sized TransContinental® Spacer and gently insert into the intervertebral space”

<u>NUVASIVE XLIF PROCEDURE</u>	<u>GLOBUS LLIF PROCEDURE</u>
	
	

46. “Once the [XLIF] procedure is completed, the Access Driver is removed while using direct visualization to verify the absence of significant bleeding in the disc space or psoas muscle. The skin is closed using standard subcuticular suture.”

47. The Globus TransContinental Surgical Technique instructs surgeons that once the procedure is complete, all blades of the retractor are returned “to the closed position by compressing the three release tabs on the back and sides of the retractor. The Interdiscal Shim

must be retrieved before removing the retractor from the body to avoid damaging tissue during retractor removal.”

COUNT 1 – INFRINGEMENT OF THE '057 PATENT

48. NuVasive incorporates and realleges Paragraphs 1-47 of this Complaint as if repeated verbatim in this Paragraph.

49. On April 6, 2010, the PTO issued United States Patent Number 7,691,057 B2 entitled “Surgical Access System and Related Methods.” (“the '057 patent”). The '057 patent was assigned by its named inventors or their legal representatives to NuVasive. NuVasive holds all right, title and interest in and to the '057 patent. A copy of the '057 patent is attached to this complaint as Exhibit A.

50. Globus has made, used, offered for sale, sold in and/or imported into the United States medical instruments, surgical implants and techniques, including instruments and implants sold under the trademarks LLIF, TransContinental[®] and MARS[®] 3V, related equipment, disposables and the LLIF technique (“Accused Products and Techniques”) that infringe, induce infringement, and/or contribute to the infringement of one or more claims of the '057 patent in violation of NuVasive’s exclusive rights to the inventions claimed by the '057 patent. Globus’ infringement is ongoing.

51. On information and belief, Globus was aware of and had actual notice of the '057 patent at the time it engaged in its directly and indirectly infringing activities. On information and belief, Globus sold and/or offered for sale the Accused Products and Techniques to hospitals, surgeons, and other health-care professionals, and actively encouraged them to use the Accused Products and Techniques in a manner that Globus knew to be infringing. On information and

belief, those hospitals, surgeons, and other health-care professionals have in fact used the Accused Products and Techniques in an infringing manner.

52. Globus, in violation of 35 U.S.C. §271(a) has directly infringed and is directly infringing the '057 patent by making, using, selling and offering for sale the Accused Products and Techniques in the United States.

53. On information and belief, Globus, in violation of 35 U.S.C. §271(b) has induced and is actively and knowingly inducing the direct infringement of the '057 patent by intentionally aiding and abetting third parties to use the invention of the '057 patent through its making, using, promoting, selling or offering for sale the Accused Products and Techniques in the United States.

54. Globus' infringement arises at least in part because Globus instructs surgeons to use the Accused Products and Techniques to perform a method of accessing a surgical target site within a spine, comprising the steps of:

- a. creating a distraction corridor along a lateral, trans-psoas path to a targeted lumbar spinal disc in a lumbar spine using a distraction assembly comprising at least two dilators that are sequentially inserted along the lateral, trans-psoas path to the targeted lumbar spinal disc;
- b. slidably advancing a plurality of retractor blades of a retraction assembly along an outermost dilator of the at least two dilators of the distraction assembly, the retraction assembly comprising a handle assembly coupled to the plurality of retractor blades such that the retractor blades extend generally perpendicularly relative to arm portions of the handle assembly, each of said plurality of retractor blades having a generally concave inner face and a generally convex exterior face, said handle assembly being capable of moving said plurality of retractor blades from a closed position to an open position, said closed position being characterized by

said plurality of retractor blades being positioned to abut one another and form a closed perimeter, said open position characterized by said plurality of retractor blades being positioned generally away from one another and forming an open perimeter;

c. simultaneously introducing said plurality of retractor blades over the outermost dilator of said distraction assembly along the lateral, trans-psoas path to the targeted lumbar spinal disc while in said closed position;

d. actuating said handle assembly to move said plurality of retractor blades to the open position so that the plurality of retractor blades create an operative corridor along the lateral, trans-psoas path to the targeted lumbar spinal disc;

e. releasably engaging a fixation element with at least one of the plurality of retractor blades so that a distal portion of the fixation element extends distally from the at least one retractor blade and penetrates into a lateral aspect of the lumbar spine, wherein the fixation element secures the at least one retractor blade to the lumbar spine;

f. inserting an implant through the operative corridor created by the plurality of retractor blades along the lateral, trans-psoas path to the targeted lumbar spinal disc.

55. On information and belief, Globus knew the Accused Products and Techniques to be especially made or especially adapted for use in a manner infringing the '057 patent, and not a staple article or commodity of commerce suitable for substantial non-infringing use. On information and belief, hospitals, surgeons and other health-care professionals have in fact used the Accused Products and Techniques in an infringing manner.

56. Globus has infringed and is infringing the claims of the '057 patent with knowledge of NuVasive's rights in the '057 patent. Globus' acts of infringement have been and are willful and deliberate in that Globus has acted despite an objectively high likelihood that its

actions constituted direct and/or indirect infringement of a valid patent. On information and belief, Globus knew or should have known of the objectively high likelihood that its actions constituted direct and/or indirect infringement of a valid patent.

57. Globus' direct and indirect infringement has injured NuVasive and NuVasive is entitled to recover damages adequate to compensate for such direct and indirect infringement, including the recovery of lost profits and in no event less than a reasonable royalty for Globus' use of the invention claimed by the '057 patent.

58. Globus' direct and indirect infringement of the '057 patent has irreparably injured NuVasive and will continue to injure NuVasive unless and until the Court enters an injunction prohibiting Globus and those acting on its behalf from committing further acts of direct and indirect infringement by enjoining the further use, offer for sale, sale, and importation into the United States of the Accused Products and Techniques.

COUNT II – INFRINGEMENT OF THE '801 PATENT

59. NuVasive incorporates and realleges Paragraphs 1-58 of this Complaint as if repeated verbatim in this Paragraph.

60. On October 26, 2010, the PTO issued U.S. Patent No. 7,819,801 ("the '801 patent"), filed as Patent Application No. 10/789,797 ("the '797 application"), entitled "Surgical Access System and Related Methods." The '801 patent was assigned by its named inventors or their legal representatives to NuVasive. NuVasive holds all right, title and interest in and to the '801 patent. A copy of the '801 patent is attached to this complaint as Exhibit B.

61. Globus has made, used, offered for sale, sold in and/or imported into the United States the Accused Products and Techniques, including instruments and implants sold under the trademarks LLIF, TransContinental[®] and MARS[®] 3V, related equipment, and disposables that

infringe, induce infringement, and/or contribute to the infringement of one or more claims of the '801 patent in violation of NuVasive's exclusive rights to the inventions claimed by the '801 patent. Globus' infringement is ongoing.

62. On information and belief, Globus was aware of and had actual notice of the '797 application and the resulting '801 patent at the time it engaged in its directly and indirectly infringing activities. On information and belief, Globus sold and/or offered for sale the Accused Products and Techniques to hospitals, surgeons, and other health-care professionals, and actively encouraged them to use the Accused Products and Techniques in a manner that Globus knew to be infringing. On information and belief, those hospitals, surgeons, and other health-care professionals have in fact used the Accused Products and Techniques in an infringing manner.

63. Globus, in violation of 35 U.S.C. §271(a) has directly infringed and is directly infringing the '801 patent by making, using, selling and offering for sale the Accused Products and Techniques in the United States.

64. On information and belief, Globus, in violation of 35 U.S.C. §271(b) has induced and is actively and knowingly inducing the direct infringement of the '801 patent by intentionally aiding and abetting third parties to use the invention of the '801 patent through its making, using, promoting, selling or offering for sale the Accused Products and Techniques in the United States.

65. On information and belief, Globus knew the Accused Products and Techniques to be especially made or especially adapted for use in a manner infringing the '801 patent, and not a staple article or commodity of commerce suitable for substantial non-infringing use. On information and belief, hospitals, surgeons and other health-care professionals have in fact used the Accused Products and Techniques in an infringing manner.

66. Globus has infringed and is infringing the claims of the '801 patent with knowledge of NuVasive's rights in the '801 patent. Globus' acts of infringement have been and are willful and deliberate in that Globus has acted despite an objectively high likelihood that its actions constituted direct and/or indirect infringement of a valid patent. On information and belief, Globus knew or should have known of the objectively high likelihood that its actions constituted direct and/or indirect infringement of a valid patent.

67. Globus' direct and indirect infringement has injured NuVasive and NuVasive is entitled to recover damages adequate to compensate for such direct and indirect infringement, including the recovery of lost profits and in no event less than a reasonable royalty for Globus' use of the invention claimed by the '801 patent.

68. Globus' direct and indirect infringement of the '801 patent has irreparably injured NuVasive and will continue to injure NuVasive unless and until the Court enters an injunction prohibiting Globus and those acting on its behalf from committing further acts of direct and indirect infringement by enjoining the further use, offer for sale, sale, and importation into the United States of the Accused Products and Techniques.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff NuVasive, Inc. prays for the following relief against Globus:

1. For judgment in favor of NuVasive that Globus has infringed and is infringing the '057 and '801 patents;
2. For a permanent injunction prohibiting Globus, including its officers, agents, employees, and all persons acting in concert or participation with them who receive actual notice of the Court's Order, from committing further acts of infringement, including direct

infringement, inducing infringement of, or contributing to the infringement of the '057 and '801 patents;

3. For an award of damages for Globus' infringement of NuVasive's '057 and '801 patents, including lost profits and/or a reasonable royalty, together with interest (both pre-and post-judgment), costs and disbursements as fixed by this Court under 35 U.S.C. § 284;

4. For a determination that Globus' infringement has been and is willful;

5. For an award of treble the amount of damages and losses sustained by NuVasive as a result of Globus' infringement, under 35 U.S.C. § 284;

6. For a determination that this is an exceptional case within the meaning of 35 U.S.C. § 285;

7. For an award to NuVasive of its reasonable attorneys' fees;

8. For an accounting for damages; and

9. For such other and further relief in law or in equity to which NuVasive may be justly entitled.

JURY DEMAND

NuVasive demands trial by jury.

Dated: October 26, 2010

FISH & RICHARDSON P.C.

By: /s/ Tara D. Elliott

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